

Virginia Regulatory Town Hall

Emergency Regulation Agency Background Document

Agency Name:	Department of Health
VAC Chapter Number:	12 VAC 5-65
Regulation Title:	Rules and Regulations Governing Durable Do Not Resuscitate Program
Action Title:	Amendment of existing rules in accordance with an emergency provision in SB 1174 (Acts of Assembly, 1999, Chapter 814, cl. 2)
Date:	11/10/99

Section 9-6.14:4.1(C)(5) of the Administrative Process Act allows for the adoption of emergency regulations. Please refer to the APA, Executive Order Twenty-Four (98), and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the emergency regulation submission package.

Emergency Preamble

Please provide a statement that the emergency is necessary and detail the nature of the emergency. Section 9-6.14:4.1(C)(5) of the Administrative Process Act states that an "emergency situation" means: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date. The statement should also identify that the regulation is not otherwise exempt under the provisions of § 9-6.14:4.1(C)(4).

The statement also should include a brief summary of the emergency regulation or emergency amendments to an existing regulation. There is no need to state each provision or amendment, instead give a summary of the emergency action.

These emergency regulations are necessary because Section 54.1-2987 of the Code of Virginia requires that the regulations be in effect within 280 days from enactment, and the regulations are not exempt under the provisions of subdivision C4 of Section 9-6.14:4.1. Because this statute became effective July 1, 1999, the regulations must in place by January 3, 2000. Briefly, the amendments will create a document -- a Durable Do Not Resuscitate Order -- that will depend less on the situation in which declarants find themselves and will be more likely to be honored.

The General Assembly, in its wisdom, has concluded that regulations to govern Durable Do Not Resuscitate Orders is essential to protect the health, safety or welfare of citizens.

Patients in consultation with physicians determine advanced directives concerning terminal illness and/or life sustaining measures. With a Durable Do Not Resuscitate Order, the affected patient is allowed to have some measure of control over his or her illness and/or injury through determination not to employ life-sustaining measures. These regulations will establish a process that enables qualified health care providers to respond more appropriately to the expressed desires and needs of certain patients. The regulations will also provide an appropriate framework to guide the operation of this important program.

Basis

Please identify the state and/or federal source of legal authority to promulgate the emergency regulation. The discussion of this emergency statutory authority should: 1) describe its scope; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. Full citations of legal authority and web site addresses, if available for locating the text of the cited authority, shall be provided.

Please provide a statement that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the emergency regulation and that it comports with applicable state and/or federal law.

Section 54.1-2991 of the Code of Virginia contains mandatory language authorizing the State Board of Health to promulgate the proposed regulations. Specifically, the Code states “[t]hat the Board of Health shall promulgate regulations to implement the provisions of this act related to Durable Do Not Resuscitate Orders to be effective within 280 days of its enactment.”

Section 54.1-2987 C of the Code specifies that qualified emergency medical services personnel and licensed health care practitioners in any facility, program or organization operated or licensed by the Board of Health or by the Department of Mental Health, Mental Retardation and Substance Abuse Services or operated, licensed or owned by another state agency are authorized to follow Durable Do Not Resuscitate Orders that are *issued in accordance with statute and regulations promulgated by the Board of Health and available to them in a form approved by the Board.*

Legal counsel in the Office of the Attorney General has certified that the agency has the authority to promulgate these regulations.

Substance

Please detail any changes, other than strictly editorial changes, that would be implemented. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Include citations to the specific sections of an existing regulation being amended and explain the differences that would be the effect of the proposed changes. The statement shall set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of citizens. The statement should also delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

Permanent regulations will be developed to replace these proposed emergency regulations, which will be amendments to existing Rules and Regulations Governing the EMS Do Not Resuscitate Program adopted in 1995.

The proposed emergency regulations establish a Durable Do Not Resuscitate (DDNR) Order that follows the patient throughout the entire health care setting. Once issued by a physician for his

patient, the DDNR Order would apply wherever that patient may be – home, emergency vehicle, adult care residence, nursing home or hospital. EMS Do Not Resuscitate Orders (DNR) provided for in the existing EMS DNR regulations apply only in the out of hospital setting.

Part I (section 12VAC5-XX-10) of the proposed regulations contains definitions of key words and terms used throughout the body of the proposed regulations. The definition of "attending physician", which was included in the existing EMS DNR regulations, is not included in the proposed regulations. This is because the existing regulations allowed only attending physicians to issue EMS DNRs, whereas the proposed regulations allow DDNR Orders to be issued by "a physician for his patient with whom he has a bona fide physician /patient relationship as defined in the guidelines of the Board of Medicine." This change in definition was dictated by the enabling statute for each set of regulations.

The definition of "qualified health care personnel" is included in the proposed regulations. Those personnel, which are authorized to honor DDNR Orders, are defined as licensed health care personnel, and include qualified emergency medical services personnel. The definition excludes certified health care personnel. The definition of "qualified health care personnel" is not included in the existing EMS DNR regulations because those Orders could be honored only by qualified emergency medical services personnel.

Part II (sections 20 through 60) contains provisions relating to the authority, purpose, administration, application and effective date of the proposed regulations. These sections are identical in the proposed regulations and the existing EMS DNR regulations, except for the stated effective date of January 3, 2000 in the proposed regulations.

Part III (sections 70 through 90) has provisions that address the content and distribution of the DDNR Order Form, revocation of a DDNR Order and allowance of alternate forms of DDNR Order identification. The DDNR Order Form is included as part of the proposed regulations. The proposed regulations state that altered DDNR Orders cannot be honored by health care personnel. There are also provisions that clarify that the regulations do not limit the issuance of or authorization of practitioners to follow Do Not Resuscitate Orders other than DDNR Orders for patients who are currently admitted to a hospital or other health care facility.

There are several differences in the Part III provisions in the proposed regulations and the existing EMS DNR regulations, as follows: 1)The proposed regulations contain a provision stating that the DDNR Order shall be completed by a physician on a patient with whom he has a bona fide established physician/patient relationship. The existing EMS DNR regulations indicate the DNR Order shall be completed by the attending physician. 2) The proposed regulations state that the DDNR Order shall remain valid until revoked. The existing EMS DNR regulations limit the effectiveness of the EMS DNR to one year. 3) The proposed regulations specify that a DDNR Order is valid in any facility, program or organization operated or licensed by the State Board of Health, or by the Department of Mental Health, Mental Retardation and Substance Abuse Services or operated, licensed or owned by another state agency. The existing regulations limit the validity of the EMS DNR Orders to qualified

EMS personnel; therefore, they can be honored only in out of hospital settings. 4) The proposed regulations contain a DDNR Order Form and allow the use of authorized alternative forms of Durable DNR Order identification approved by the State Board of Health. The existing regulations contain a DNR Order Form and also allow a bracelet.

Part IV (sections 100 and 110) contain implementation procedures for DDNR Orders. Specifically, procedures relating to the following are included: issuance of the Order, confirmation of DDNR Order validity status, resuscitative measures to be withheld or withdrawn, provision of comfort care or alleviation of pain, revocation of Orders, documentation in the patient's medical record of care withheld or rendered, and general considerations outlining implementation when there are misunderstandings or questions about the validity of DDNR Orders or other DNR Orders. The provisions in these sections in the proposed regulations are essentially the same as the corresponding provisions in the existing EMS DNR regulations. The one substantive difference is that a provision in the proposed regulations, as authorized by the enabling statute, allows the issuance of DDNR Orders for minors; the EMS DNR regulations do not allow issuance of DNRs for minors.

Alternatives

Please describe the specific alternatives that were considered and the rationale used by the agency to select the least burdensome or intrusive method to meet the essential purpose of the action.

In light of the clear, specific and mandatory authority of the State Board of Health to promulgate the proposed regulations, the Board has not considered any alternatives to the proposed regulations, nor is any warranted. The Board has, however, carefully drafted the proposed regulations to ensure that they embody the most appropriate, least burdensome and least intrusive framework for effectively administering the Durable Do Not Resuscitate Program.